



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 31 2000 7 9 8 0 '00 FEB -8 P 1:58

Marc S. Ullman, Esq.
Ullman, Shapiro & Ullman, L.L.P.
299 Broadway
Suite 1700
New York, New York 10007

Dear Mr. Ullman:

This is in response to your letter to the Food and Drug Administration (FDA) dated January 6, 2000, on behalf of Traco Labs, Inc., concerning claims being made for their product "Cholestatin."

In your letter, you expressed the opinion that claims concerning cholesterol reduction do not necessarily relate to hypercholesterolemia and, consequently, are not disease claims prohibited under 21 U.S.C. 343(r)(6). You also asked whether cholesterol reduction claims could be made for conventional foods. Your letter included some promotional material for a conventional food that bears cholesterol reduction claims.

In your letter, you stated that not all claims about cholesterol reduction relate to hypercholesterolemia. You stated, for example, that some persons may have "high normal" cholesterol levels that do not constitute hypercholesterolemia but that should, nonetheless, be reduced. In this case, you argued that a cholesterol lowering claim would be an appropriate claim under 21 U.S.C. 343(r)(6) because such a person is not suffering from a disease condition (i.e., hypercholesterolemia).

We disagree. Section 343(r)(6) prohibits claims to prevent disease as well as claims to treat an existing disease. Therefore, a claim to prevent hypercholesterolemia by lowering cholesterol in the "high normal" range is not authorized under 21 U.S.C. 343(r)(6). Moreover, FDA published a final rule in the January 6, 2000 Federal Register (65 FR 1000) defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. In the preamble to that final rule, we stated that the agency considers claims about lowering cholesterol to be implied disease claims that are not claims permitted under 21 U.S.C. 343(r)(6) (see discussion at 65 FR 1019). Consequently, we continue to believe that the claims we identified in our December 7, 1999 letter to Traco Labs, Inc. are not claims authorized in supplement labeling under 21 U.S.C. 343(r)(6).

975-0163

See LET 322
LET 328

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Thank you for the information that you provided us about cholesterol reduction claims for a competing product marketed as a conventional food. As a matter of policy, FDA does not comment on the safety, label or labeling, or claims made for a product with parties other than the responsible firm. We evaluate all such information provided to us and take appropriate action based on the results of our evaluation and available resources and enforcement priorities.

With regard to our general policy on structure and function claims for conventional foods, please refer to the preamble to the January 6, 2000 final rule. As discussed on page 1034, that while that rule applies only to claims being made for dietary supplements under 21 U.S.C. 343(r)(6) that for consistency, the agency is likely to interpret the dividing line between structure/function claims and disease claims in a similar manner for conventional foods. Consequently, cholesterol-lowering claims made for conventional foods may also be implied disease claims.

If we can be of further assistance to you in this matter, please contact us.

Sincerely,

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements

cc:

HFA-224 (w/incoming)

HFC-200

HFR-MW140

HFD-310 (Williams)

HFD-314 (Aronson)

HFS-22 (CCO)

HFS-450 (w/control slip, OSN#68754, r/f)

HFS-456 (r/f, Moore w/cpy incoming)

r/d:HFS-456:RMoore:1/14/00

revised per GCF-1:LNickerson:1/19/00

revised per GCF-1:LNickerson:1/20/00

revised/init:GCF-1:LNickerson:1/21/00

f/t:HFS-456:RJM:1/31/00:DocName:68754.OSN:Disc44

68754
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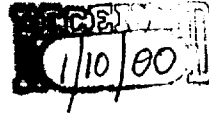
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January 6, 2000

Certified Mail - Return Receipt Requested

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Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Office of Food Safety and Applied Nutrition
United States Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

Re: Traco Labs, Inc. Section 403(r)(6) Notification

Dear Dr. Larsen:

We are counsel for Traco Labs, Inc. ("Traco") and are writing in connection with the courtesy letter dated December 7, 1999 sent to Traco over Robert Moore's signature. In that letter, your office advised Traco that it considered the claim "helps reduce bad cholesterol levels" an improper claim for a product marketed as a dietary supplement, in that it "suggests that it is intended to treat, prevent, or mitigate a disease, nameiy hypercholesterolemia." While Traco will, for now, accept your suggestion that it not make this claim on behalf of its Cholestatin product, we wish to raise two significant issues concerning Dr. Moore's December 7 letter.

First, claims concerning cholesterol reduction do not necessarily relate to hypercholesterolemia. According to most sources, individuals with cholesterol levels in excess of 230mg would be classified as suffering from hypercholesterolemia, placing them at a significant risk for heart disease. On the other hand, while individuals with cholesterol levels in the 200mg range (generally considered "high normal") cannot be classified as suffering from any disease condition, they almost certainly would be advised by their physicians to undertake a program of diet and exercise designed to lower their cholesterol levels. We believe that there are no provisions in the Federal Food, Drug and Cosmetic Act that would prohibit cholesterol reduction claims directed at individuals in this latter category. So long as cholesterol-lowering

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Director

Division of Programs and Enforcement Policy

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claims are properly substantiated and are not directed at individuals actually suffering from a disease condition (hypercholesterolemia), we believe that they constitute proper structure/function claims and that FDA's efforts to prohibit this type of communication reflect the agency's unfortunately myopic view of the nature of the important health benefits that may be offered by dietary supplements.

Second, we note that there are a plethora of other products supported by major marketing programs on the basis of cholesterol-lowering claims. One prominent example of this are the very explicit claims made by McNeil Consumer Healthcare on behalf its Benecol product. These claims include:

- "A delicious New Way to **Reduce** Your Cholesterol"
- "the new line of foods that actually **reduce bad cholesterol up to 14%!**"
- "Doctor-recommended Benecol Spread is a revolutionary new food that **reduces** 'bad' cholesterol (LDL) up to **14%**"
- "The proven ability of Benecol foods to lower cholesterol is supported by **over 20 studies . . .**"
- "Benecol Spread is the first of many great-tasting Benecol foods that actually reduce cholesterol . . ."
- "Unlike other foods that are just low in cholesterol, Benecol foods are actually proven to **reduce** cholesterol levels."
- "you can reduce your total cholesterol up to 10% . . ."
- "'if your total cholesterol is 230, Benecol could lower your cholesterol by as much as 23 points!"

Copies of the Internet pages on which these statements appear are enclosed for your consideration.

We would greatly appreciate your advising us of the propriety of claims such as these, especially in light of the courtesy letter sent to Traco in connection with its proposed claim "Helps reduce bad cholesterol levels." Though Traco's product is marketed as a dietary supplement, and Benecol is marketed as a conventional food, our client views McNeil's product as a major marketplace competitor that may now have a significant marketing advantage due to

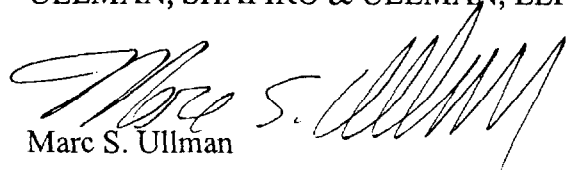
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FDA enforcement policies. We believe that there can be no rational basis for any enforcement policy that would restricted truthful and nonmisleading claims on behalf of a dietary supplement on the grounds that such claims constitute "drug claims," while permitting the same or substantially similar claims to be made on behalf of a conventional food.

Thank you for your prompt consideration.

Very truly yours,
ULLMAN, SHAPIRO & ULLMAN, LLP


Marc S. Ullman

Encl.

cc: Dr. Robert Moore
Sid Tracy, President, Traco Labs, Inc.



Benecol

*A Delicious New Way to
Reduce Your Cholesterol*



Welcome



Benecol



Well
New! Recipes



We're glad you are interested in Benecol foods, the new line of foods that actually **reduce bad cholesterol up to 14%**! Simply enjoy 3 servings of any Benecol product each day in place of similar foods.



Club
Benecol

Now
\$1.00 Coupon



Now

Benecol

TRY OUR NEW
PRODUCTS -
Dressings,
Snack Bars, and
new Spread Tubs!



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*A New Way to Manage
Your Cholesterol ...*

Benecol



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About

Doctor-recommended Benecol Spread is a revolutionary new food that **reduces** "bad" cholesterol (LDL) up to **14%*** while maintaining good cholesterol (HDL) levels. It can start to work in just **2 weeks!**

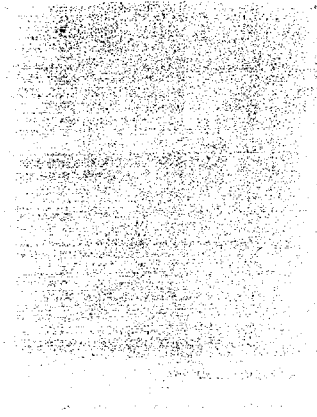
The proven ability of Benecol foods to lower cholesterol is supported by **over 20 studies**, including one reported in the New England Journal of Medicine and a U.S. study led by researchers at the Mayo Clinic.

Doctors are recommending Benecol Spreads to their patients. Benecol food can be used in cholesterol-lowering diets, even for those who are on cholesterol-lowering medications.

Benecol Spread is just the first of many great-tasting Benecol foods that actually reduce cholesterol and can start to work in just 2 weeks. Benecol Dressings and Snack Bars are available in your local store now. Other delicious Benecol foods are on their way to make reducing your cholesterol even more enjoyable!

The name Benecol brings together Bene, meaning "good" and col, for "cholesterol." Benecol offers you a new way to reduce your cholesterol with delightfully good-tasting foods.

Unlike other foods that are just low in cholesterol, Benecol foods are actually proven to **reduce** cholesterol levels. By eating three servings of any Benecol foods a day in place of similar foods you can reduce your total cholesterol up to 10% - which means if your



total cholesterol is 230, Benecol could lower your cholesterol by as much as 23 points! Better still, Benecol foods taste fabulous so it's simple and delicious to include them in your daily diet.

To learn more about great-tasting Benecol foods and the ***unique ingredient*** in Benecol foods, we've provided you with information on how Benecol works as well as answers to commonly asked questions about Benecol and cholesterol management.

*Use 3 servings of any Benecol product each day in place of similar foods.